# Safe Medical Treatments: Everyone Has a Role
## *Ensuring the safety of drugs, biologics, and medical devices in health care*

A workshop co-sponsored by the Food and Drug Administration (FDA)
and the National Patient Safety Foundation (NPSF)

March 27-28, 2000

Workshop Summary

## Introduction

**Janet Woodcock, M.D.,** Director, Center for Drug Evaluation and Research, FDA, welcomed participants to the workshop. She pointed out that discussions about the safe use of medical products that led to the Institute of Medicine's report, *To Err Is Human*, failed to include "the consumer voice and the voice of patient groups." The two-day workshop co-sponsored by the Center (http://www.fda.gov/cder) and the National Patient Safety Foundation (http://www.npsf.org) was intended to be the first step at informing consumer and patient groups and obtaining their feedback about this important public health problem. About 100 persons attended.

The workshop consisted of:

- Background information
- A panel discussion of personal encounters with using drugs safely
- A briefing on the current risk management system
- A video and panel discussion of the problems the health care system has in using medical products safely and achieving solutions that avoid placing blame
- Opportunities for open discussion as well as public testimony about personal encounters with medical product safety problems
- A panel discussion from representatives of consumer groups on strategies to influence the system to improve access and safe use of medical products
- Breakout sessions to discuss a variety of organizational strategies and methods to influence risk management.
- A "town hall" meeting to discuss partnering issues and future directions.

## Background: Defining the Problem

**John Urquhart, M.D.,** Chief Scientist, AARDEX Ltd., Union City, CA, and Professor of Pharmaco-epidemiolgy at Maastricht University, Netherlands, briefly outlined key events in drug

development-from the first major human vaccinations in 1786 to the discovery of effective AIDS treatments in the 1990s. “Americans struggle with the tangled semantics of the term ‘safe,’ when applied to medicine,” he said. “Safe is a booby-trapped term. The common meaning of safe is ‘risk-free.’ So nothing is safe. There are only degrees of safety.”

According to Urquhart, prescription drugs are a cornerstone of economic health care; however, their effectiveness relies on reasonably good compliance with the labeled regimen. That compliance is often lacking. One study shows that only 27 percent of patients have control of their blood pressure. Only one in three patients stay on their correct drug regimen. Patients miss doses, fail to take their medicine as directed, or stop taking their medicine completely once they “feel better” despite directions to finish the medicine.

Urquhart said that the pharmaceutical community needs to embrace the automotive industry’s vision of consumer protection. Before 1975, he said, the common view of auto executives was that they could quality control any part of the automobile “except the nut behind the wheel.” In the last two decades, however, many innovations in car design aim at protecting drivers from their own mistakes, including seat belts, airbags, computer-controlled electronics and anti-lock braking systems.

The good news, Urquhart said, is that the pharmaceutical industry has embraced the concept of the patient as the customer and is developing ways to track patient dosing histories and possible drug-drug interactions. The bad news, he said, is that the industry is still ignoring information about the effects on patients using drugs at full dose, still struggling to determine what to do when a patient misses a dose and is still unsure about the effects of patients taking a drug holiday, sometimes for weeks at a time.

**Panel: Personal Perspectives**

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| Moderator: | **Stephen Fried,** author; editor, Philadelphia Magazine |
| Panelists | **Kay Jamison, Ph.D.,** author; professor, Johns Hopkins University |
| | **Judi Herishen,** patient |

**Stephen Fried** noted that the consumer’s struggle to take medicine safely is common to all pill takers. Fried discussed his wife’s serious adverse reaction to a single dose of an antibiotic and the couple’s subsequent involvement with consumers and risk management issues.

**Kay Jamison, Ph.D.,** Professor and author related her 10-year struggle to comply with lithium therapy for her manic depression. Once her symptoms went away, her desire and incentive to take her medicine went away. Only after recovering from a suicide attempt did she resolve never to stop her lithium.

**Judi Herishen** described her saga to maintain health despite an autoimmune disorder and two kidney transplants. Following the second transplant, a new anti-rejection medication caused severe adverse reaction.

**Risk Management System**

The system of risk management for medical products in the United States is poorly integrated and outdated, said Dr. Woodcock. As a consequence, substantial preventable harm occurs. Estimates are that as many as 98,000 people may die each year from medication errors in hospital settings. Framing the issue as a "regulatory problem" ignores reality, she said. It's too easy to punish the presumed guilty and not change the fundamentals, she said. A concerted effort by all constituents is required to change the system, she said. She outlined the sources of risk and the risk management system as discussed in *Managing the Risks form Medical Product Use: Creating a Risk Management Framework.* This report to the FDA Commissioner from the FDA Task Force on Risk Management is available on the World Wide Web at: http://www.fda.gov/oc/tfrm/1999report.html.

**Panel: "Don't Point Fingers"**

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| Moderator: | **Eleanor Vogt, R.Ph., Ph.D.,** Senior Fellow<br>National Patient Safety Foundation |
| Panelists: | **Jim Conway,** Chief Operating Officer, Dana-Farber Cancer Institute<br>**Robert Hohlman,** NAMI (formerly National Alliance for the Mentally Ill)<br>**Arnold Gordon, Ph.D.,** Pfizer Inc.<br>**Jim Reed,** Diabetics Educating and Empowering Diabetics<br>**Terry Short, R.Ph.,** CVS Pharmacy<br>**Andrew Smith, J.D.,** AARP<br>**Dorothy Smith, Pharm.D.,** Consumer Health Information<br>**Martha Solonche, M.A.,** SHARE<br>**David Flockert, M.D.,** American Society for Clinical Pharmacology and Therapeutics |

**Eleanor Vogt, R.Ph., Ph.D.,** Senior Fellow National Patient Safety Foundation, reviewed the foundation's Rx Safe Use Initiative and its resulting 41-step action plan. The Safe Medical Treatments Workshop was one of the actions identified in that plan. Further, the workshop was unique because it was planned entirely by patients and consumers—the ultimate end users of medical products. Dr. Vogt urged everyone to remember the student teacher's motto in understanding the true nature of learning: "Tell me—I will forget. Show me—I may remember. Involve me—I will understand."

**Jim Conway,** Chief Operating Officer, Dana-Farber Cancer Institute, Boston, discussed his organization's response to a widely publicized medical error, which claimed the life of a Boston Globe medical reporter after a massive overdose of chemotherapy. His organization instituted a patient and family advisory committee that gives patients a voice in organizational matters such as reviews of medication errors, treatment protocols and patient education. Conway, who came to

Dana-Farber from a background in pediatric care, said adult care needs the equivalent of the "mother in your face" who demands to know what is being done to her child and why.

**Arnold Gordon, Ph.D.,** Pfizer Inc., outlined steps the pharmaceutical industry is taking to eliminate errors and develop solutions. There are a number of actions that the pharmaceutical industry is exploring to reduce potential problems, such as: more sophisticated examination of product names to avoid confusion, use of an improved method of bar-coding products used in a hospital setting, better use of color and package size to aid product differentiation and a redesign of labeling. In addition, Gordon called for an increase in health literacy and numeracy so patients and health care providers can understand directions and take action on regimens.

**David Flockhart, M.D.,** Georgetown Medical Center, Washington, DC, explained the difficulties of conducting research into patient risk and safety. He and other panelists discussed the breakdowns in communication that can occur between patients and their health care providers and among the health care team that takes care of a single patient.

**Terry Short,** CVS Pharmacy, said that community pharmacists are among the most accessible medication experts and try to remain available for counseling. This remains a challenge with an increasing volume of prescriptions. Most pharmacies use real time software checks for safety issues such as drug-drug interactions and drug-allergy interactions. She encouraged patients use of same pharmacist so drug histories can be tracked.

**Dorothy Smith, Pharm.D.,** Consumer Health Information, pointed to the need to bridge the gap between health care providers and patients. Consumers decide when medicine is taken in the home environment. Without reliable information, many will make serious errors. When information is presented accurately, consumers can make informed decisions. However, too many people are managing their treatments incorrectly and are not being told how to manage the side effects of their medications. As a result, people are dying from home medication errors. The cost to treat home medication errors is more that what is spent on all prescription drugs, she said. She recommended the use of patient information sheets and extensive use of simplified medical illustrations.

**Andrew Smith, J.D.,** AARP, said that patients need to be involved in arriving at solutions and that consumer organizations may have to rethink how they work with other organizations with which they have had tense relationships.

**Martha Solonche, M.A.,** SHARE, pointed out that there is a great difference in care given to those who are alert and ask about their treatments. By being aware of what is going on around them, patients can improve their entire situation.

**Jim Reed,** Diabetics Education and Empowering Diabetics, said that a diabetic has to be his or her own best advocate. A patient needs to know why he or she is taking a medicine. Patients need to go to their health care professionals with a list of medications. Patients need to be convinced that they are in charge of their illness and the care team.

**Robert Bohlman,** NAMI, commented that all problems related to patient safety are compounded in someone who is cycling down. Modern medications offer improved functioning with fewer side effects. However, some formularies emphasize older, less expensive drugs that have more side effects. Consequently, these policies can create more compliance problems.

**Panel: Influencing the System**

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| Moderator: | **Theresa A. Toigo, R.Ph, MBA,** Associate FDA Commissioner for Special Health Issues |
| Panelists: | **Linda Golodner,** National Consumers League |
| | **Annette Drummond,** Arm in Arm |
| | **Jeff Jacobs,** AIDS Action Council |
| | **Albert van der Zeijden,** International Alliance of Patients Organizations |

**Theresa A. Toigo, R.Ph., MBA,** Associate FDA Commissioner for Special Health Issues, said that the health care delivery system is relatively new at dealing with risk information "Consumers must learn the language of risk," she said. "If not, medical experts will be making decisions that consumers should."

**Linda Golodner,** National Consumers League, noted that it is important that communicators avoid developing messages about using medical products safely in an ivory tower. Communicators must involve the audience they are trying to reach, and they must get people involved at the grass-roots level, find everyone who could have a major role, and then have everyone buy into the issue.

**Annette Drummond,** Arm in Arm, described an outreach effort that generated state government support for a federal mammogram program. In 1990, the federal government funded a state program to provide free mammograms for low income, uninsured women. States were to match $1 for every $3 in federal dollars. One state government funded the support as a pilot program in the expectations that it would convince the hospitals to provide the necessary matching fees in order to reduce uncompensated care. When the pilot ended, this did not happen; in fact, some hospitals started charging patients for the service. Drummond described the organizational and grass-roots efforts needed to restore state funding for the program.

**Jeff Jacobs,** AIDS Action Council, discussed how consumer involvement was the key AIDS activists used to gain expanded access to experimental therapies and faster FDA approval of drugs to treat AIDS. After scaling the walls of the FDA, activists sat down with officials to discuss what members of the AIDS community needed. The new policies have benefited all patients with serious and life-threatening illness that lack adequate treatment. For consumers using AIDS drugs now, safety is the issue because the drugs have tremendous side effects and strict regimens. Patient support groups are an important resource for individuals learning to use the drugs correctly.

**Albert van der Zeijden,** International Alliance of Patients Organizations, discussed efforts in Europe to develop patient-centered health care. Physicians see patient information as a better way to obtain compliance, he observed. However, patients see information as a way to come to a better judgment about the advice from their physicians. Instead of informed consent, he offered "negotiated consent" as the model for the future. This model attempts to fit the drug regimen into the lifestyle of the patient.

## Town Hall Meeting

Dr. Vogt declared the workshop a historic meeting that brought sunshine on the issue. Dr. Woodcock emphasized the need to figure out the next steps. Participants observed that this was the first conference between health care providers and consumers that evidenced a collaborative spirit. The participants strongly agreed that they cared about the problem of safe use, but everyone struggled with defining the one solution that would have the greatest impact. The conference steering committee pledged to try to articulate the missing links in the pharmaceutical safety chain identified throughout the program, They will feed their thinking back to all the participants. The steering committee also explained that the program was a pilot to determine what message should be taken to consumer and patient group leaders and what resources and assistance these leaders would need to educate their own membership. It was agreed that continued dialogue on this public health issue is critical and needs to take place within all stakeholder groups.

## Workshop Steering Committee/Contacts

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| **Co-chairs** | |
| Janet Woodcock | Center for Drug Evaluation and Research, FDA |
| Eleanor Vogt | National Patient Safety Foundation |
| **Members** | |
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| Stephen Fried | Author |
| Linda Golodner | National Consumers League |
| James J. Reed | Diabetics Educating and Empowering Diabetics |
| Andrew Smith | American Association for Retired Persons |
| Martha Solonche | SHARE |
| Lorrie Harrison<br>Mary Meyer | Center for Biologics Evaluation and Research, FDA |
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